NATIONAL PBM DRUG SAFETY ALERT DISTRIBUTION

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy for the dissemination of drug-related safety communications from the Food and Drug Administration (FDA) and other credible sources to providers and when appropriate, to patients.

2. BACKGROUND

a. The Pharmacy Benefits Management (PBM) Services office receives drug-related safety information from a variety of sources including the FDA, manufacturers, and wholesalers. These include a number of different alerts, such as drug recalls, shortages, labeling changes, and new information for providers and patients. This Directive establishes a consistent method for the dissemination of drug-safety information. In instances where a closed loop confirmation is required due to the gravity of the alert, assurance that the communications were received and that actions were completed is required.

b. **Definitions**

- (1) **National PBM Bulletin.** A National PBM Bulletin is a Drug Safety Alert that includes standard sections: Issue, Background, Recommendations, and References. It is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Bulletin include provider notification, as well as actions to be carried out by the provider. When warranted, recommended actions include patient notifications by phone call, in person, or by letter. Confirmation that actions have been completed will be required.
- (2) **National PBM Communication.** A National PBM Communication is a Drug Safety Alert that does not include standard sections, but is warranted to further clarify and/or emphasize what is noted in the drug-related safety information. It is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Communication include provider notification and when warranted, patient notifications by phone call, in person or by letter. When warranted, confirmation that actions have been completed is required.
- (3) **Drug Safety Alert Mail Group.** The Drug Safety Alert Mail Group is a mail group consisting of the Deputy Under Secretary for Health for Operations and Management (10N), Veterans Integrated Service Network (VISN) Directors, VISN Chief Medical Officers, Chiefs of Staff, Patient Care Services (11) representatives, Nurse Executives, Consolidated mail-out

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Pharmacy (CMOP) Directors, Primary Care Chiefs-Directors, Medical Advisory Panel (MAP) members, VISN Formulary Leaders (VFL), Chiefs of Pharmacy Services, and representatives from Pharmacy ReEngineering (PMO), the National Center for Patient Safety (NCPS), Network Patient Safety, Emergency Preparedness, Public Affairs (10C3), the Office of Research and Development (ORD), and the Office of Research Oversight (ORO).

- (4) **Safety Notices (PBM) Mail Group.** The Safety Notices (PBM) Mail Group is a national mail group composed primarily of senior pharmacists and representatives from the Department of Vetertans Affairs (VA) research community.
- (5) **VAMedSAFE.** VAMedSAFE is a PBM Center for Medication Safety with a mission to identify, track and address preventable adverse drug events (ADEs) in the VA system with the primary focus on preventing adverse drug reactions (ADRs). Goals are to identify and verify adverse events (AEs) using pharmacovigilance or postmarketing surveillance, track AEs and effect of intervention, enhance education and communication of AEs and potential AEs on a national level, institute and promote risk reduction efforts, and promote medication safety research in VA.
- **3. POLICY:** It is VHA policy that PBM develop and disseminate Drug Safety Alerts within specified time frames and, when appropriate, collect feedback from specified field representatives to ensure all communications were received and actions have been completed. **NOTE:** PBM does this in cooperation with MAP, VAMedSAFE, ORD, and field-based experts.

4. ACTION

- a. <u>Deputy Under Secretary for Health for Operations and Management.</u> The Deputy Under Secretary for Health for Operations and Management (10N) is responsible for ensuring that VISN Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents (see Att. A).
- b. <u>VISN Director</u>. Each VISN Director is responsible for any required communication to PBM or VAMedSAFE as directed in the Drug Safety Alert documents. *NOTE:* Responses are required within 10 business days of receipt.
 - c. Facility Director. The facility Director, or physician designee, is responsible for:
- (1) Ensuring that a facility Medical Staff process is in place to comply with this Directive, and
 - (2) Disseminating Drug Safety Alert documents within the facility, and
- (3) Confirming document dissemination and follow-up action to the VISN Director when required.
 - d. Facility Chief of Staff (COS). The facility COS is responsible for:

- (1) Disseminating all Drug Safety Alerts and related materials to all providers and individual designees within their facility, including the Associate Chief of Staff (ACOS) for Research and Development (R&D).
- (2) Ensuring that all required actions are completed, including mailing patient letters when directed.
 - (3) Organizing and maintaining detailed records of:
- (a) Medical center providers and other designees to whom Drug Safety Alerts are sent (including date and time);
 - (b) Individuals designated to contact patients (when required); and
- (c) A list of patients who were notified of the Drug Safety Alert by their providers or designees, where applicable. The date and time of notification must be included.
- (4) Communicating to the facility Director that all required actions were completed within the designated timeframe.
 - e. ACOS for R&D. The ACOS for R&D is responsible for:
- (1) Disseminating Drug Safety Alerts and related materials to all Principal Investigators (PIs) who have authority to practice at the medical center;
- (2) Communicating the Drug Safety Alert information to their respective Institutional Review Board (IRB); and
- (3) Communicating to the facility COS that all required actions were completed within the designated timeframe (see subpar. 4b).
- f. Pharmacy Benefits Management (PBM) Services. PBM is responsible for designating specific Clinical Pharmacists, who are responsible, in cooperation with Medical Advisory Panel (MAP), VAMedSAFE, and when appropriate, ORD, and field-based experts, for developing Drug Safety Alerts with provider notification, recommended actions (when appropriate) and, when warranted, patient letters. Confirmation from the VISN Director is collected by PBM and VAMedSAFE to ensure all communications were received and recommended actions have been completed within 10 business days. Non-responders are reported to Deputy Under Secretary for Health for Operations and Management (10N) for follow-up.
- g. <u>Associate Chief Consultant, PBM Services.</u> The Associate Chief Consultant, PBM Services, or designee, is responsible for:

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- (1) Ensuring that the PBM FDA Liaison Pharmacist forwards all new drug safety information to the Safety Notices (PBM) Mail Group.
- (2) Ensuring that PBM Clinical Pharmacists, VAMedSAFE,MAP, and Field experts review drug safety information and identify the need for dissemination to the Drug Safety Alert Mail Group. This includes:
 - (a) Determining if a Drug Safety Alert is appropriate; and
- (b) Determining the type of Drug Safety Alert (e.g., National PBM Bulletin, National PBM Communication).
- (3) Ensuring that PBM Clinical Pharmacists, VAMedSAFE, MAP, and Field experts develop Drug Safety Alerts, as deemed appropriate, with recommended actions (e.g., patient letters when warranted) using the following process:
 - (a) The PBM Clinical Pharmacist responsible for the disease state or the Drug Class must:
- <u>1</u>. Provide written information in response to the alert including pertinent background information;
- <u>2</u>. Prepare any supplemental clinical information ensuing from the Alert recommendations (e.g., Patient Letter templates); and
- <u>3</u>. Consult with field experts (Technical Advisory Groups (TAG), Chiefs of Pharmacy Services, etc.) when field input is necessary for the development and completion of these documents.
 - (b) The VAMedSAFE Staff is responsible for:
- <u>1</u>. Preparing Drug Safety Alert topics involving drugs or disease states that are not assigned to a PBM Clinical Pharmacist,
 - 2. Identifying a set of recommendations to address the drug safety concern, and
 - 3. Reviewing all drafts and providing feedback and edits when necessary.
- (4) Ensuring the dissemination of Drug Safety Alerts to the Drug Safety Alert Mail Group within 10 business days, once sufficient evidence has been collected.
- (5) Ensuring that the Drug Safety Alert and related materials are posted on the PBM website and the VAMedSAFE web page.
- (6) Ensuring the maintenance of all records confirming the completed dissemination of documents and actions from each VISN Director.

- h. <u>Field Experts.</u> Field experts (TAG, Clinical Advisory Groups, Chiefs of Services, etc.) are responsible for reviewing drafts, when consulted, and providing feedback and edits where necessary.
- i. <u>Original Author.</u> The Original Author of the Safety Alert is the owner of the Safety Alert and, as such, incorporates all edits, changes, and revisions. In addition, the Original Author of the Safety Alert is responsible for:
- (1) E-mailing the finalized Safety Alert and related materials to the Associate Chief Consultant PBM, or designee, for electronic distribution to the Drug Safety Alert Mail Group; and
- (2) Summarizing the Safety Alert for inclusion in the VISN Formulary Leaders Committee and Medical Advisory Panel agendas for the next scheduled conference call or face-to-face meeting. *NOTE:* Agenda items must list the PBM clinical pharmacist's name and the VAMedSAFE designee's name as the responsible individuals for the Safety Alert topic.
- **5. REFERENCES.** None.
- **6. RESPONSIBLE SERVICE:** Pharmacy Benefits Management Services (119) is responsible for the contents of the Directive. Questions may be addressed to 202-461-7326.
- **7. RESCISSION:** VHA Directive 2008-075, dated November 5, 2008 is rescinded. This VHA Directive expires November 30, 2013.

Michael J. Kussman, MD, MS, MACP Under Secretary for Health

DISTRIBUTION: CO: E-mailed 11/18/08

FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/18/08

ATTACHMENT A

NATIONAL PBM DRUG SAFETY ALERT DISTRIBUTION ALGORITHM

